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(54) **Pressure/temperature/flow monitoring device for vascular implantation**

(57) A medical monitoring apparatus designed to be implanted in the vascular system is capable of sensing and transmitting via a telemetry link to an external monitor both pressure and temperature information. An internally or externally powered microcircuit component is supported on a stent-like structure and adapted to be placed in the vascular system. Placement in the ventricular septum permits measurement of pressure and temperature in the left ventricle without introducing thrombus generating materials in the left ventricle.

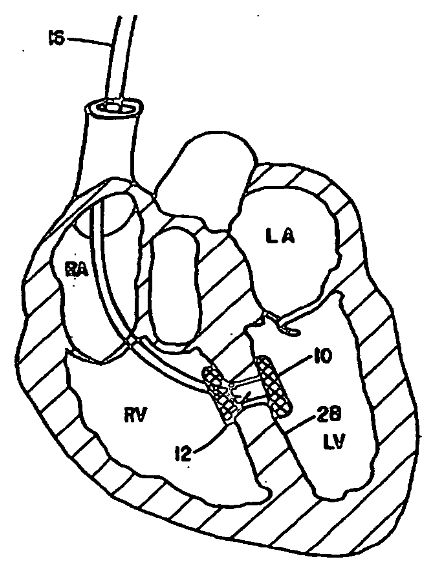

FIG. 3

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Description

Background of the Invention

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This is a continuation-in-part of application Serial Number 09/303,634, filed May 3, 1999.

[0002] I. Field of the Invention This invention relates generally to medical apparatus for monitoring physiologic parameters within the body of a human or other animal, and more particularly to an implantable device for chronic monitoring of pressure, flow and temperature within living humans or animals.

[0003] II. Discussion of the Prior Art: In the diagnosis and treatment of various maladies, a variety of devices have been developed which can be implanted within the body and used to monitor various physiologic parameters. With the advent of microminiature circuitry, it has become practical to implant a variety of sensors responsive to various physiologic changes, along with circuitry for the transcutaneous transmission of information from the implanted unit, via a telemetry link to an external recording/display device. For example, in the field of implantable cardiac pacemakers and defibrillators, sensing circuitry is incorporated therein for monitoring a number of physiologic parameters, such as respiratory rate, tidal volume, heart rate, blood temperature, movement, etc. Pacemaker leads have been developed that incorporate pressure transducers and temperature sensors such that the pacing rate of the implanted device can be made to vary in relation to detected changes in blood temperature and blood pressure.

[0004] In implementing such devices, the electronic circuitry is housed in a body compatible, fluid impervious housing along with a suitable power supply or AC to DC converter and electrical leads are then routed from the implant site and through the vascular system to a location on or in the heart. Because of concern that the presence of a lead in the left ventricular chamber may result in the formation of a thrombus that could break loose and reach the brain and cause stroke or embolize to another peripheral vessel, pacing leads or other devices are seldom inserted into the left ventricle, especially for chronic monitoring or therapy delivery.

[0005] The ability to measure left ventricular pressure or its surrogate in the ambulatory patient, non-invasively, has great potential in determining the status of heart failure patients, providing an opportunity to modify medical management of ventricular dysfunction very precisely as compared to current clinical practice. Moreover, ambulatory hypertensive patients can be managed more closely when peak systolic and diastolic pressure can be chronically monitored.

[0006] The ability to measure myocardial temperature with an implanted device and to thereafter telemeter the temperature information to an external monitor will permit cardiac transplant patients to be closely managed. It is believed that rejection in organ transplant patients manifest early as a small tissue temperature elevation due to the inflammatory reaction of rejection. The only presently available method to determine transplant status is to perform a biopsy, an invasive procedure that is sometimes done weekly or more often, and is done in such a patient hundreds of times during that patient's life. A device for measuring tissue temperature and telemetering the information to an external monitor would limit the number of times such biopsy is required--a significant clinical advance.

[0007] Myocardial temperature sensing is beneficial in the management of heart failure. Ventriculo-vascular coupling and impedance mismatches manifest themselves as excess heating of the ventricle. By having temperature monitoring available, accurate titration of preload and afterload reducing medication could be achieved to limit myocardial energy output and thereby the heart will perform more efficiently. Therefore, a need exists for a system for chronically monitoring temperature and pressure within the left ventricular and/or atrial chambers of the heart or myocardial tissue.

[0008] It has also determined that a temperature sensor located in the pulmonary artery branches for sensing lung tissue temperature can provide meaningful information following heart/lung transplant surgery in that an elevated blood or lung tissue temperature in the pulmonary artery or branches may be indicative of the onset of rejection, allowing interventional adjustment in the amount of anti-rejection drug being administered to the patient. We are presently unaware of any temperature sensor that can be chronically implanted to measure temperature changes in blood traversing the pulmonary artery.

[0009] By locating the monitor implant at other locations within the body, renal, hepatic or pancreas transplant status can be assessed. Locating the device in the peripheral blood vessels can allow assessment of exercise capacity. The monitor may also be used to calculate blood flow using thermodilution techniques.

[0010] From the foregoing, it can be seen a need exists for an implantable sensor especially designed for placement in a selected portion of a patient's vascular system and which can be used to chronically transmit pressure and/or temperature data to an external monitor/display unit so that a medical professional can more readily diagnosis and treat various medical conditions. It is principal object of the present invention to fulfill this need.

SUMMARY OF THE INVENTION

[0011] In accordance with the present invention there is provided a medical monitoring apparatus that comprises a support member that is adapted for chronic implantation at a predetermined location within the vascular system of a living human or other animal. One or

more sensor devices are affixed to the support means for sensing at least one measurable physiologic parameter. The apparatus further includes a means for telemetrically transmitting signals representative of the sensed parameter percutaneously to an external signal receiver. In accordance with one embodiment of the invention, the support means may comprise a self-expanding or balloon expandable tubular stent that is adapted for chronic implantation at a predetermined location in the vascular system and affixed to the tubular stent is an electronic circuit for measuring a physiologic parameter. The electronic circuit means also includes a means for telemetrically transmitting signals representative of the sensed parameter percutaneously to a signal receiver external to the body of the living animal.

[0012] To measure left ventricular pressure/temperature, the apparatus of the present invention may be placed in an puncture made through the ventricular septum with the stent being anchored in this opening, such that the pressure/temperature sensor is exposed to blood or tissue in the left ventricle. An anchoring arrangement is provided on the stent to prevent the normal pumping action of the heart from displacing the implanted stent. To prevent blood flow through the tubular stent, the lumen thereof may be packed with a fibrous material for occluding the opening. The electronics module may also be located in the lumen if occlusion is desired.

[0013] If the stent device is to be placed in the pulmonary or some other artery of a patient, the anchoring means may comprise a series of hooks that become engaged with the inner wall of the artery when the stent is allowed to or made to expand radially during its implantation.

DESCRIPTION OF THE DRAWINGS

[0014] The foregoing features, objects and advantages of the invention will become apparent to those skilled in the art from the following detailed description of a preferred embodiment, especially when considered in conjunction with the accompanying drawings in which like numerals in the several views refer to corresponding parts.

Figure 1 is a perspective view showing a tubular stent as a support member for an electronic circuit package for sensing and telemetrically transmitting sensed pressure and temperature data and powered by an implantable power pack;

Figure 2 is an end view of the device of Figure 1;

Figure 3 is a sectioned view through the heart showing the monitor device of the present invention located in the ventricular and atrial septum;

Figure 4 is a schematic diagram illustrating apparatus for applying power to an implanted unit percutaneously; and

Figure 5 is a block diagram of the integrated circuit chip forming a part of the implantable monitor apparatus.

DESCRIPTION OF THE PREFERRED EMBODIMENT

[0015] Referring first to Figure 1, there is illustrated a first embodiment of a temperature/pressure monitoring device adapted for placement at a desired location within the vascular system of a living animal. It is seen to comprise a support member 10, here shown as a self-expandable or balloon expandable stent, to which is attached an electronics module 12 that is adapted to be powered by an implantable power source 14 connected to it by means of conductors 16. The power source 14 is preferably a lithium-iodide battery contained within a body fluid impervious housing 18. The electronic circuitry comprising the module 12 is also contained within a body fluid impervious housing 20 having sealed electrical feed-throughs 22 to which the conductors 16 are attached for bringing DC power into the module.

[0016] As will be further explained, associated with the electronics module 20 are one or more sensors for detecting changes in a physiologic parameter such as blood temperature, blood pressure or flow. The sensor may comprise a pressure sensor of the type described in the Brockway et al. Patent 4,846,191, either alone or in combination with a thermistor temperature transducer and a Doppler flow sensor.

[0017] Formed on opposed ends of the stent 10 are retention elements, shown in Figure 2 as hooks 26 which are adapted to engage tissue to prevent migration of the device from its desired implant site. The need for retention elements is, of course, somewhat dependent on the location selected for the implant.

[0018] The sectional view taken through a heart illustrated in Figure 3 shows the way in which the present invention can be used to monitor either left ventricular pressure or left atrial pressure on a chronic basis. Here, an incision is made through the ventricular septum 28 or the atrial septum 30 with a device like that shown in Figure 1 percutaneously implanted via an artery or vein and inserted into the surgically created opening. The support device 10, itself, may comprise a septal defect occluder fashioned after that described in the Kotula et al. U.S. Patent 5,725,552 but with an electronics module 12 mounted thereon. The sensor element is exposed to the blood in the left ventricle and/or the left atrial chamber depending on the placement of the device. The support device 10 may be delivered by way of a catheter routed through the vascular system into the right ventricle and thence through the surgically created septal opening. When the device 10 is released from the confines of the catheter, it self-expands to a predetermined dumbbell configuration, as illustrated, to maintain it in position in the septal wall. Alternatively, in an open heart surgery, the device of Figure 1 can be inserted through the myocardium of the left ventricle or left atrium.

[0019] When disposed in the lumen of a blood vessel, the support device 10 is tubular as shown in Figure 1, permitting blood flow therethrough. The hooks 26 on opposed ends thereof serve to anchor the device in place in the selected blood vessel. Placement of the stent with its temperature/pressure/flow measuring circuitry in the pulmonary artery or a branch thereof can be used to obtain a good estimation of left ventricular end diastolic pressure which is meaningful in the treatment of CHF and hypertension. It is calibrated by direct comparison with left ventricular pressure measured with an acutely placed pressure sensing catheter. Periodic recalibration can be accomplished via software.

[0020] Figure 4 illustrates an alternative embodiment of the invention wherein the implant device may receive its operating power transcutaneously from a programmer transducing head 32 supported on a shoulder strap 34 which keeps the transducing head is oriented in alignment with the implanted device. The transducing head 32 may be of the type used in the telemetry link of a programmable implantable pacemaker allowing the patient to be ambulatory. The transmitting and receiving electronics and the battery power supply therefore may be contained in a case 36 worn on a belt surrounding the patient's abdomen. Information developed by the sensor 24 of the implant device 10 is telemetered to the external transducer 32 via RF transmission and is fed to the electronic module 36 for signal processing, storage and later analysis.

[0021] Figure 5 is a block diagram illustrating the circuitry contained within the housing 20 of the implant device. The output signals from the aforementioned pressure/ temperature/flow transducers can readily be separated into two channels, one for carrying the pressure information and the other for carrying temperature information by appropriate filtering techniques, it being recognized that the output signal from the pressure sensor will be of a significantly greater frequency than that from the temperature sensor. Hence, in Figure 5, both a pressure sensor 50 and a temperature sensor 52 are illustrated to indicate the dual channel nature, even though a single transducer device may be utilized. The analog output signal from both the pressure sensor 50 and the temperature sensor 52 are applied to an analog-to-digital converter forming a part of the on-board microprocessor 54. The microprocessor 54 includes an address bus 56, a data bus 58 and a control bus 60 to which are connected a ROM memory 62, a RAM memory 64 and an input/output interface 66. ROM 62 conventionally stores a program executable by the microprocessor 54 while RAM 64 may store programmable constants and intermediate data developed during the execution of the program. The I/O interface is attached to a telemetry circuit 68, allowing data carried on the data line 58 from the microprocessor and/or the RAM to be transmitted transcutaneously from the patient's body, represented by dashed-line 70 to an external monitor 72. The monitor 72 may be conveniently be a lap-top PC having the ability to receive and process the telemetry data from the implant and to deliver programming data to the implant device, via the telemetry link.

[0022] The temperature transducers illustrated in Figures 1 and 2 may comprise a thermistor, or thermocouple or an infrared sensor. A separate piezoelectric device can be utilized as a pressure sensor in a fashion indicated in the Brockway Patent 4,846,191. It is also contemplated that a separate flow sensor may be made a component of the implantable monitor device or, alternatively, the temperature sensor may be used to assess flow using known thermodilution techniques.

[0023] This invention has been described herein in considerable detail in order to comply with the patent statutes and to provide those skilled in the art with the information needed to apply the novel principles and to construct and use such specialized components as are required. However, it is to be understood that the invention can be carried out by specifically different equipment and devices, and that various modifications, both as to the equipment and operating procedures, can be accomplished without departing from the scope of the invention itself.

Claims

1. Medical monitoring apparatus comprising:

   (a) support means adapted to be chronically implanted at a predetermined location in the vascular system of a living animal;
   (b) means affixed to the support means for sensing at least one measurable parameter; and
   (c) means on the support means for telemetrically transmitting signals representative of the sensed parameter percutaneously to a signal receiver.

2. Medical monitoring apparatus comprising:

   (a) a tubular stent adapted for chronic implantation at a predetermined location in the vascular system of a living animal;
   (b) electronic circuit means affixed to said tubular stent for measuring at least one measurable parameter; and
   (c) means in the electronic circuit means for telemetrically transmitting signals representative of the sensed parameter percutaneously to a signal receiver exterior of the living animal.

3. The medical monitoring apparatus as in Claim 2 wherein the measurable parameter is selected from a group consisting of blood temperature, blood flow and blood pressure.

4. The medical monitoring apparatus as in Claim 3 wherein the tubular stent has first and second ends and a lumen extending therebetween, the first end adapted for placement in a left cardiac chamber with the second end extending through a portion of the cardiac septum into a right cardiac chamber.

5. The medical monitoring apparatus as in Claim 4 and further including an occluder disposed in the lumen.

6. The medical monitoring apparatus as in Claim 4 wherein the left cardiac chamber is a left atrial chamber and the right cardiac chamber is a right atrial chamber.

7. The medical monitoring apparatus as in Claim 4 wherein the left cardiac chamber is a left ventricular chamber and the right cardiac chamber is a right ventricular chamber.

8. The medical monitoring apparatus as in Claim 2 wherein the electronic circuit means includes means for sensing intravascular pressure and the means for telemetrically transmitting signals comprises means for transmitting signals representative of the sensed intravascular pressure.

9. The medical monitoring apparatus as in Claim 2 wherein the electronic circuit means includes means for sensing intravascular temperature and the means for telemetrically transmitting signals comprises means for transmitting signals representative of intravascular temperature.

10. The medical monitoring apparatus as in Claim 6 wherein the electronic circuit means includes means for sensing pressure in one of the left atrial chamber and the myocardium.

11. The medical monitoring apparatus as in Claim 7 wherein the electronic circuit means includes means for sensing pressure in one of the left ventricular chamber and the myocardium.

12. The medical monitoring apparatus of Claim 6 wherein the electronic circuit means includes means for sensing temperature in one of the left atrial chamber and myocardium.

13. The medical monitoring apparatus of Claim 7 wherein the electronic circuit means includes means for sensing temperature in one of the left ventricular chamber and myocardium.

14. The medical monitoring apparatus of Claim 2 wherein the tubular stent comprises an antenna connected to the electronic circuit means for transmitting said signals.

15. The medical monitoring apparatus of Claim 2 wherein the tubular stent is self-expandable.

16. The medical monitoring apparatus of Claim 2 wherein the tubular stent is balloon expandable.

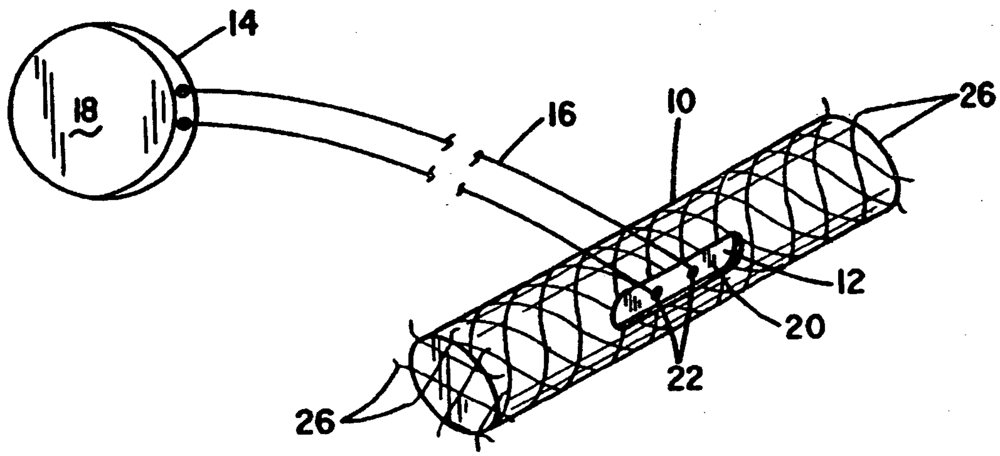

FIG. 1

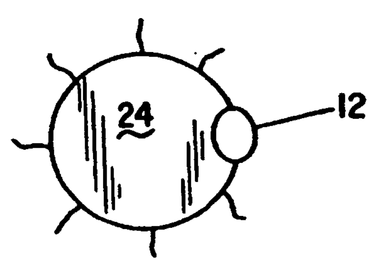

FIG. 2

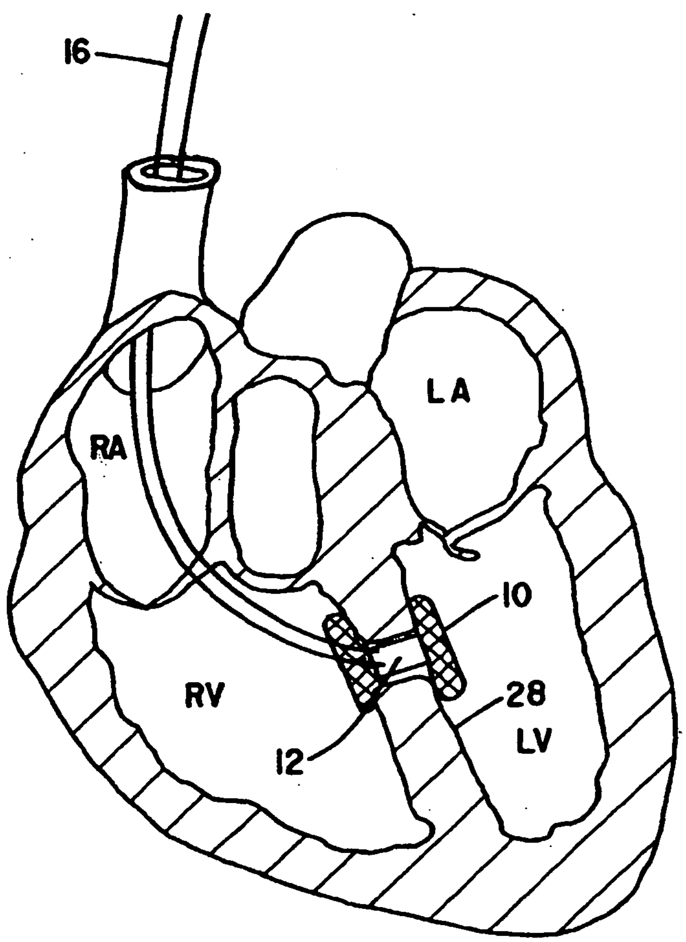

FIG. 3

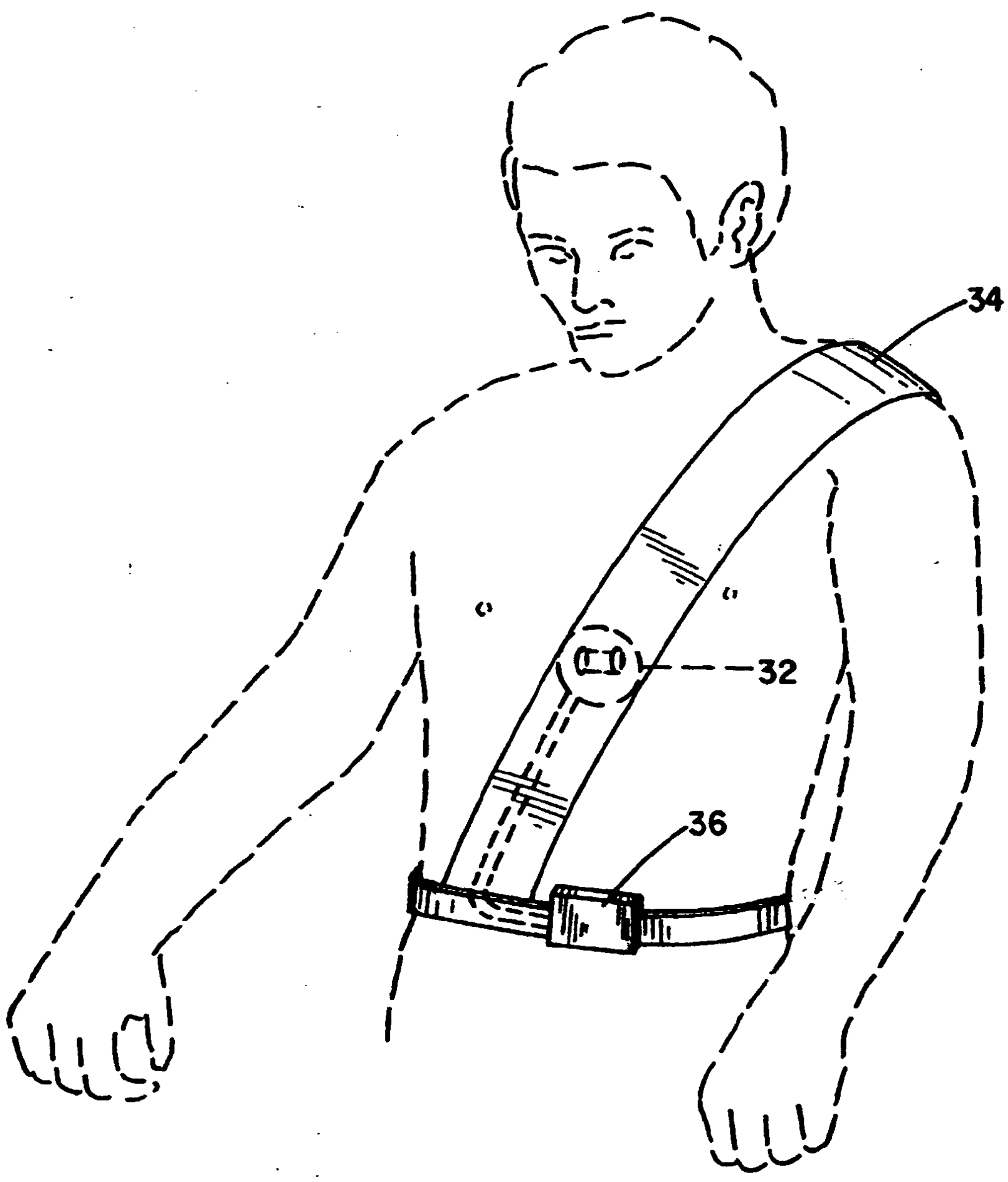

FIG. 4

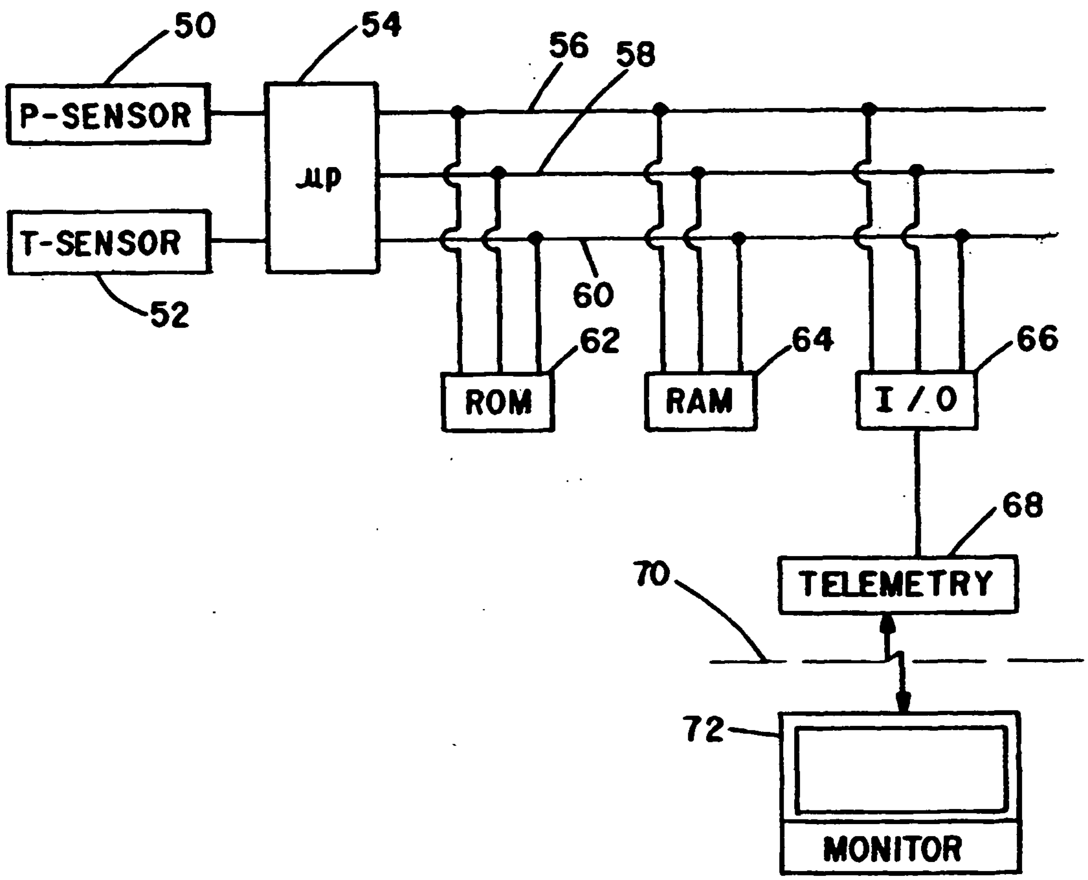
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FIG. 5

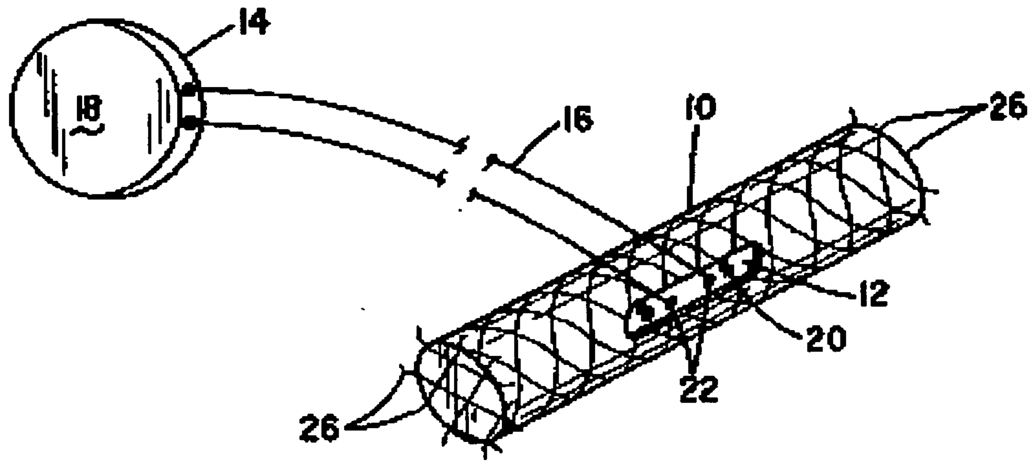

FIG. 1

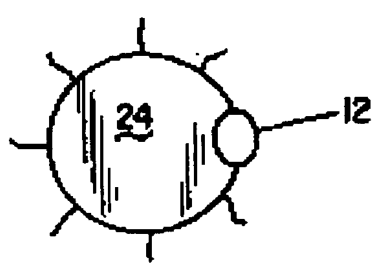

FIG. 2

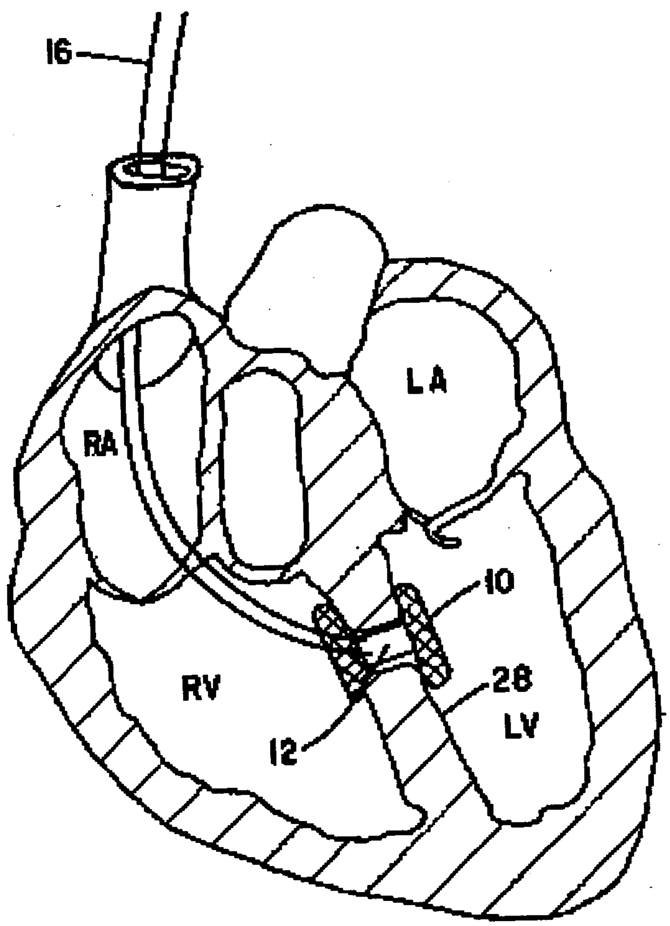

FIG. 3

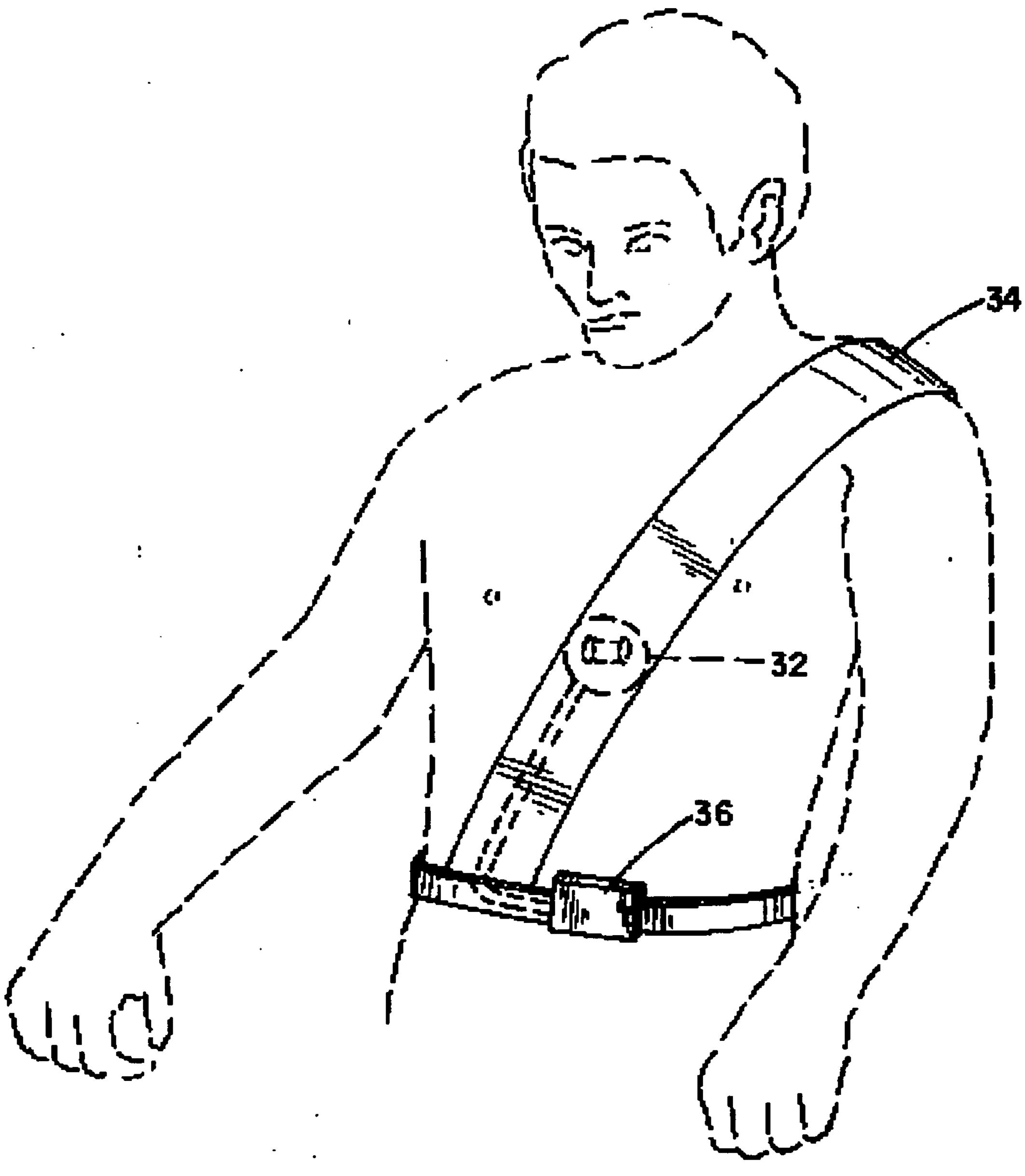

FIG. 4

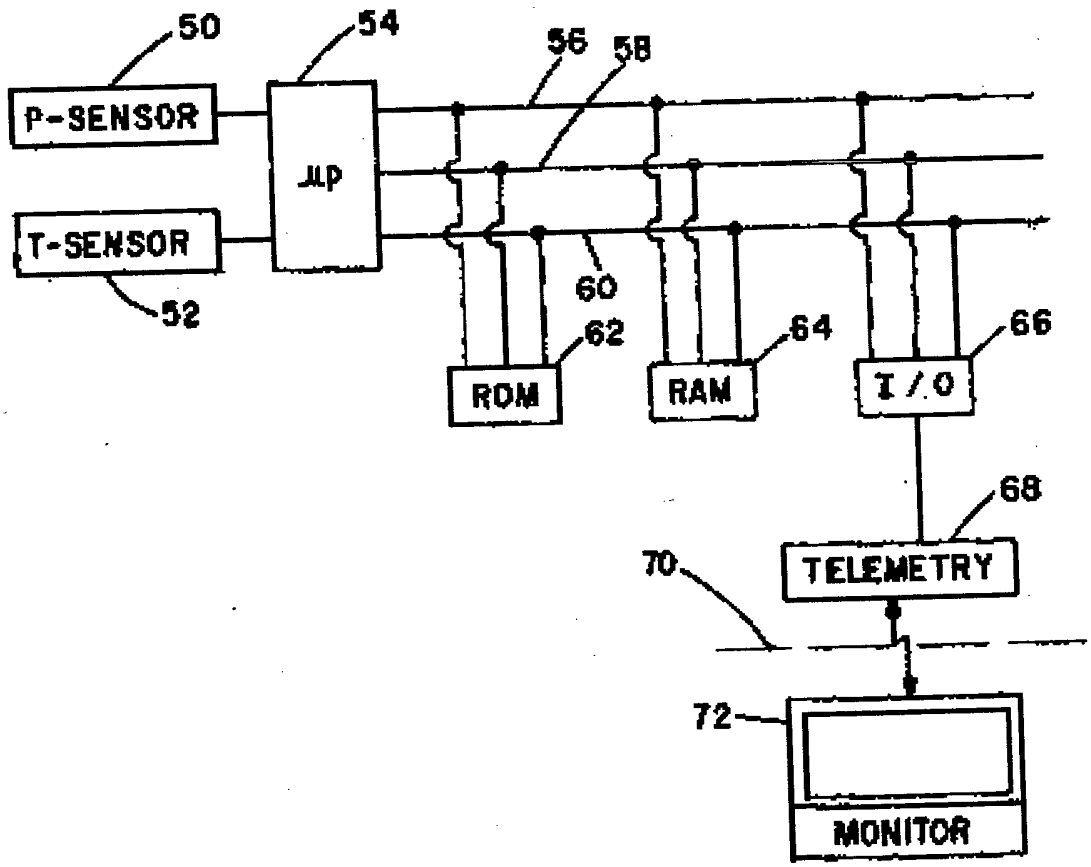
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FIG. 5